

## REMARKS

### I. Introduction

In the Advisory Action dated August 22, 2003, the Examiner denied entry of the foregoing amendments. In the Examiner's opinion, the amendments raised new issues that would require additional consideration and searching, and in any event did not reduce or simplify the outstanding issues. By way of the present Request for Continued Examination, therefore, Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

### II. Status of the Claims and Summary of Amendments Thereto

By way of the foregoing amendments, claims 58, 65 – 78, and 82 – 119, are cancelled, without prejudice or disclaimer thereof. Applicants reserve the right to prosecute the subject matter of the cancelled claims in this or another application. Claims 1 – 50 were cancelled previously. New claims 120 – 131 are added. Thus, following entry of this Amendment, claims 51- 57, 59 – 64, 79 – 81, and 120 – 131 are pending for examination on the merits.

Claim 51 is amended to incorporate the administration period of claim 79 and to recite the limitations of cancelled claims 58, 118, and 119; specifically, to recite specific drugs and a drug concentration range. Support for the administration time can be found in the specification, such as at page 13, lines 21-24. Claim 52 is amended to recite a composition suitable for administration in 1 to 2 seconds. *See* page 7, lines 19-21; page 8, lines 2-6; and page 24, lines 5-8. Claim 59 is amended to depend from claim 51 instead of cancelled claim 59. Claim 79 is redrafted into independent form to incorporate the limitations of amended claim 51. Finally, new claims 120 – 130, which depend from method claim 79, recite the particular limitations in composition claims 52 – 57 and 60 – 64.

Applicants submit that the amendments do not introduce new matter. Therefore, Applicants courteously request entry thereof by the Examiner.

### III. The Office Action

#### A. Rejection of Claims Under 35 U.S.C. § 103

##### 1. **Wood et al., U.S. Patent No. 6,264,922**

Claims 51 – 64, 79 – 81, and 118 stand finally rejected as being allegedly obvious over Wood et al., U.S. Patent No. 6,264,922 (“Wood”). In the Examiner’s opinion, Wood discloses “all the required components and elements of [the] compositions and method of their delivery,” and therefore inherently encompasses the claimed limitation of essentially each drop comprising at least one nanoparticulate drug particle. Office Action at pages 2-3. To the extent that this rejection may apply to the claims as amended, Applicants respectfully traverse this rejection.

###### a. **Wood Does Not Teach or Suggest Applicants’ Claimed Short Administration Period**

Wood does not teach or suggest aerosol compositions that can be administered in less than about 15 seconds or methods of administering the same, as required by claims 51 and 79, respectively, or aerosol compositions that can be administered in less than about 1 to 2 seconds or methods of administering the same, as required by claims 52 and 120, respectively.

Aerosol compositions suitable for administration in short periods of time, *e.g.*, less than about 15 seconds, are highly preferred over aerosol compositions requiring multiple puffs and administration over a lengthy time period, *e.g.*, 4 to 20 minutes, to ensure that the proper quantity of drug has been administered. *See e.g.*, page 7, lines 19-21, of the application. This is because short administration periods can correlate with increased patient compliance, and thereby reduced episodes of asthma or other condition which is being treated with the aerosol composition.

Wood does not teach or suggest these features of the claimed invention.

Thus, a person of ordinary skill in the art would not have been motivated by Wood to make the claimed compositions or methods with an expectation that such compositions could

be administered in less than about 15 seconds or in about 1 to 2 seconds. Withdrawal of this ground for rejection is respectfully requested.

**b. Wood Does Not Teach or Suggest the Compounds Required by the Claims**

All of Applicants' claims are limited to compositions, and methods of administering the same, comprising naproxen, triamcinolone acetonide, budesonide, or an anti-emetic.

The general disclosure of therapeutic and diagnostic agents in Wood would not have fairly suggested the claimed invention to the artisan of ordinary skill to the extent that the claims recite specific drugs not disclosed in Wood. "The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious." *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994). Some motivation to select the claimed species or subgenus must be taught by the prior art. See *In re Deuel*, 51 F.3d 1552, 1558-1559 (Fed. Cir. 1995) and *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993).

Here, as in *Baird*, the prior art reference discloses a broad genus of compounds. See Wood at col. 3, ll. 30-31 ("wide variety of therapeutic or diagnostic agents") and col. 3, l. 45 to col. 4, l. 6 (listing categories of therapeutic and diagnostic agents). However, Wood does not teach or suggest the drugs of naproxen, triamcinolone acetonide, budesonide, and an anti-emetic recited in independent claims 51 and 79.

For the foregoing reasons, Applicants courteously request the Examiner to reconsider and withdraw this rejection.

**2. Wiedmann et al., U.S. Patent No. 5,747,001**

Claims 51 – 64, 79 – 81, and 118 stand finally rejected as being allegedly obvious over Wiedmann et al., U.S. Patent No. 5,747,001 ("Wiedmann"). The Examiner considers Wiedmann, as with Wood, to inherently teach the claimed limitation of essentially each droplet comprising at least one nanoparticulate drug particle. See Office Action dated 10/2/02 at pages 2-3. To the extent that this rejection may apply to the claims as amended, Applicants respectfully traverse this rejection.

**a. The Claims are Patentable over Wiedmann, as Wiedmann is Limited to a Drug Which is Not Encompassed by the Claims**

The analysis of the rejection pertaining to Wood above also applies to Wiedmann. However, the disclosure of Wiedmann is more limited than that of Wood to the extent that Wiedmann relates to aerosols containing dispersions of nanoparticulate beclomethasone dipropionate; aerosols of other drugs are not taught by Wiedmann. Consequently, Wiedmann does not teach or suggest Applicants' claimed invention, which does not recite beclomethasone dipropionate.

**b. The Claims are Patentable over Wiedmann, as Wiedmann Does Not Teach Administration Periods of 1-2 Seconds or Less than About 15 Seconds**

Furthermore, Wiedmann is silent as to the claimed administration times and the ability to administer aerosol compositions comprising nanoparticulate drug dispersions in less than about 15 seconds or in only 1 to 2 seconds. Thus, a person of ordinary skill in the art would not have ascertained these features of the claimed invention from the disclosure of Wiedmann. Withdrawal of this ground for rejection is respectfully requested.

**3. Wiedmann in View of U.S. Patent No. 5,985,309 to Dalby et al.**

Claims 84 – 101, 118, and 119 stand finally rejected as being allegedly obvious over Wiedmann in view of U.S. Patent No. 5,985,309 to Dalby et al. (“Dalby”). According to the Office Action dated October 2, 2002, Dalby is relied upon for teaching “delivery of beclomethasone dipropionate by metered dose inhalers containing non-CFC propellants.” Office Action dated 10/2/02 at page 5.

Because the rejected claims are cancelled by way of the present amendments, without prejudice or disclaimer thereof, Applicants respectfully submit that this rejection is moot.

**B. Provisional Obviousness-Type Double Patenting**

Applicants kindly thank the Examiner for bringing to their attention the provisional obviousness-type double patenting rejection that was inadvertently not addressed in Applicants' response dated March 3, 2003. According to the Office Action dated October 2,

2002, claims 51 – 64, 79 – 81, 84 – 101, 118, and 119 stand rejected as being obvious over the claims of copending Application Serial No. 09/190,138.

This rejection is moot with respect to cancelled claims 84 – 101, 118 and 119. As to the remaining claims, Applicants respectfully request the Examiner to hold this rejection in abeyance until such time as allowable subject matter has been indicated.

**IV. Conclusion**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. If the Examiner believes that a telephone interview would advance the prosecution of the present application, she is invited to contact the undersigned by telephone.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.